



## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/700,057	02/05/2001	Colin Brown	9052-67	1282	
20792	7590 06/02/2004		EXAMINER		
MYERS BI	GEL SIBLEY & SAJO	WHITE, EVE	WHITE, EVERETT NMN		
PO BOX 374 RALEIGH,		ART UNIT	PAPER NUMBER		
Killerin, No. 27027			1623		
			DATE MAILED: 06/02/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary    Examiner			Application	n No.	Applicant(s)			
### Deficies Action Summary  ### EVERETT WHITE   1623  The MAILING DATE of this communication appears on the cover sheet with the correspondence address  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE of THIS COMMUNICATION.  Edurances of lines may be available under the provisions of 3 CPR 1.135(a). In no event, however, may a raphy be timely tilled  If NO period for reply specified above, the maximum statistical period will apply used with signified will be communicated with the provision of the seminal patient term adjustment. Sea 3 rc Rr 1.704(b).  Status  1) M Responsive to communication(s) filled on 12 February 2004.  2a) M This action is FINAL. 2b) M This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 c.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1,2.4-10.14-18.21-24.26-35 and 39-43 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) 1,2.4-10.14-18.21-24.26-35 and 39-43 is/are rejected.  7) Claim(s) is/are as unique and application and/or election requirement.  Applicant may not request that any objection to the drawing(s) be held in abeyance. Sea 37 CFR 1.85(a).  11) The specification is objected to by the Examiner.  12) The specification is objected to by the Examiner.  13)	Office Action Summary		09/700,057		BROWN, COLIN			
Period for Reply  A SHORTEND STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Educations of time may be available under the provisions of 3 CFR 1.138(b). In an overt, however, may a reply be timely lited after 63X (6) MONTH'S from the mailing date of this communication.  If the period care says specified date in a beat that 1MT (5) days, with be considered tends, of the care of the communication in the period of the communication.  If the period care says specified date in the time that the care in the state of the period of the communication.  If the period care says specified date in the time that the care in the time of the communication o			Examiner		Art Unit			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Educations of from any be available and the providence of 37 CPT 1.136(a). In no overst, however, may a reply be limitly filed  Education of forming to evaluation and the providence of 37 CPT 1.136(a). In no overst, however, may a reply be limitly filed  Education of the major be available under the providence of 37 CPT 1.136(a). In no overst, however, may a reply be limitly filed  Education of the major be available under the providence of 37 CPT 1.136(b). In no overst, however, may a reply be limitly filed  If NO period for reply is specified above, the material valuation of 37 CPT 1.136(a). In order of 18 CPT 1.136(b). If NO period for reply is specified above, the material valuation of 18 CPT 1.136(a).  If NO period for reply is specified above, the material valuation of 37 CPT 1.736(b).  Status  1) □ Responsive to communication(s) filled on 12 February 2004.  2a) □ This action is FINAL. 2b) □ This action is non-final.  3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) □ Claim(s) 1.24 10.14 18.21 24.26 35 and 39 -43 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  5) □ Claim(s) is/are allowed.  5) □ Claim(s) is/are allowed.  6) □ Claim(s) is/are objected to.  9) □ The specification is objected to by the Examiner.  Application Papers  9) □ The specification is objected to by the Examiner.  Application Papers  10 □ The drawing(s) filed on is/are: all accepted or b □ objected to by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  11 □ The proposed drawing correction filed on is/are: all accepted or b □ objected to by the Examiner.  Priority under 35 U.S.C. § 119 and 120  13) ☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C			EVERETT	WHITE	1623			
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Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  a) The translation of the foreign language provisional application has been received.  Attachment(s)  1) Interview Summary (PTO-413) Paper No(s)  5) Notice of References Cited (PTO-992)  1) Notice of Draftsperson's Patent Drawing Review (PTO-948)  5) Notice of Informal Patent Application (PTO-152)	7) Claim(s)							
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### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 12, 2004 has been entered.
- 2. The amendment filed February 12, 2004 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
- (A) Claims 3, 11-13, 19, 20, 25, and 36-38 have been canceled;
- (B) Claims 1, 22, 23 and 39-43 have been amended;
- (C) Comments regarding Office Action have been provided drawn to:
  - (a) 112, 2<sup>nd</sup> paragraph rejection, which has been withdrawn;
  - (b) 112, 1<sup>st</sup> paragraph rejection, which has been withdrawn;
  - (c) 103(a) rejection, which has been maintained for the reasons of record.
- 3. Claims 1, 2, 4-10, 14-18, 21-24, 26-35, and 39-43 are pending in the case.
- 4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

# Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph

5. Claims 1, 2, 4-10, 14-18, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note In re Tuominen, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. In Claim 1, the passage set forth in the last 2 lines of Claim 1 describes how the composition will be used which is improper in Claims drawn to a product since such language makes the claims alternative. Hence, the language "acts as an osmotic agent

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to maintain a volume ... which otherwise may adhere to each other" should be deleted from Claim 1. This indefinite language in Claim 1 also renders claims dependent from Claim 1 indefinite. See Claims 2, 4-10, 14-18, 21, 22 and 39.

Claims 14-16, which specify the amount of dextrin in the claimed composition, are indefinite since dextrin is the only component set forth in the claimed composition.

6. Applicant's arguments with respect to Claims 1, 2, 4-10, 14-18, 21 and 22 have been considered but are moot in view of the new ground(s) of rejection.

### Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1, 2, and 4-10 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies (US Patent No. 5,258,175, already of record).

Applicant claims a composition comprising an aqueous formulation containing a polysaccharide dextrin in an amount effective to reduce adhesions, wherein the dextrin is unsubstituted and contains more than 15% of polymers with a degree of polymerization (DP) greater than 12. Additional limitations in the dependent claims include the aqueous formulation being a solution, specifying the amount of 1,6 linkages in the dextrin, specifying the number average molecular weight and weight average molecular weight of the dextrin, specifying the amount of dextrin present in the composition,

The Davies patent discloses a dextrin used to prepare a dextrin derivative that is derived from a dextrin which is a glucose polymer mixture containing at least 15%, preferably at least 50%, by weight of glucose polymers of D.P. (degree of polymerization) greater than 12. Davies discloses the dextrin as having a weight average molecular weight of from 15,000 to 25,000 (see column 2, paragraphs 1 and 2), which fall within the weight average molecular weight range disclosed in instant Claims

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8 and 9. See column 2, lines 37 and 38 of the Davies patent, wherein starch is hydrolyzed to produce dextrin, which anticipates a dextrin solution. Accordingly, the dextrin composition of the Davies patent anticipates the dextrin composition of the instant claims.

9. Applicant's arguments with respect to Claims 1, 2, 4-10 and 14-16 have been considered but are most in view of the new ground(s) of rejection.

## Claim Rejections - 35 USC § 103

- 10. Claims 1, 2, 4-10, 14-18, 21, 22 and 39-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Davies (US Patent No. 5,258,175) for the reasons set forth in the previously filed Office Actions.
- Applicant's arguments filed February 12, 2004 have been fully considered but 11. they are not persuasive. Applicants argue against the rejection on the ground that the motivation set forth in the Office Action filed February 11, 2003 for combining the Viegas et al patent with the Davies patent was not clear and particular. In response to Applicant's argument the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). A more clearer and particular motivation for combining the references is disclosed hereafter. In column 1, 2<sup>nd</sup> paragraph, the Davies patent discloses the dextrin being used as an osmotic agent. One would be motivated to combine the Viegas et al patent with the Davies patent since Viegas et al sets forth dextrin compositions that provide a physiologically acceptable vehicle having hypoosmotic, hyperosmotic, or isoosmotic characteristics. Also, Applicants argument that the Viegas et al patent sets forth compositions that are "gelled in situ" is not persuasive since the composition is in solution form prior to contact with the body. Accordingly, the rejection of the claims as

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being unpatentable over the Viegas et al patent in view of the Davies patent is maintained for the reasons of record.

- 12. Claims 23, 24 and 26-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Milner (US Patent No. 4,886,789) for the reasons set forth in the previously filed Office Actions.
- 13. Applicant's arguments filed February 12, 2004 have been fully considered but they are not persuasive. Applicant argues against the rejection on the ground that Claim 23 now recites that the dextrin is unsubstituted. This argument is not persuasive since the Viegas et al patent does not disclosed that the polydextrin set forth therein is required to have substituted groups.

Applicant further argues that the combination of the Viegas et al with the Milner patent does not teach or suggest the present invention. The Milner patent, which discloses a peritoneal dialysis composition containing an osmotic agent comprising a glucose polymer mixture - which encompassed dextrin, is cited to show that the application of such a polymer to the peritoneal cavity is well known in the art. Accordingly, the rejection of Claims 23, 24 and 26-35 under 35 U.S.C. 103(a) as being unpatentable over the Viegas et al patent in view of the Milner patent is maintained for the reasons of record.

In response to Applicant's argument that the combination of the two references may, at best, provide a film-forming peritoneal dialysis solution, the fact that Applicant has recognized another advantage, which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Accordingly, the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Viegas et al patent in view of the Milner patent is maintained for the reasons of record.

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### **Summary**

14. All the pending claims are rejected.

#### Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

## Examiner's Telephone Number, Fax Number, and Other Information

16. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at <a href="https://www.uspto.gov">www.uspto.gov</a> and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

James O. Wilson Supervisory Primary Examiner Technology Center 1600